K043068

510(k) Summary

DEC 2 9 2004

Pursuant to 512(i)(3)(A) of the Food, Drug and Cosmetic Act, Electro-Optical Sciences, Inc. is required to submit with this Premarket Notification either an "...adequate summary of any information respecting safety and effectiveness or state that information will be made available upon request of any person." Electro-Optical Sciences chooses to submit a summary of the safety and effectiveness information, as follows:

Trade Name: **DIFOTI USB 2.0 System**
(a/k/a DIFOTI System for Dental Examinations, Model B)

Owner/Operator: Electro-Optical Sciences, Inc.
1 Bridge Street, Suite 15
Irvington-on-Hudson, NY 10533

Manufacturing Site: Electro-Optical Sciences, Inc.
1 Bridge Street, Suite 15
Irvington-on-Hudson, NY 10533
Establishment Registration # 2438478

Device Generic Name: Dental examination system

Classification: According to Section 513 of the Federal Food, Drug, and Cosmetic Act, the device classification is Class I, General Controls (21 CFR 872.4620, and 872.6640). According to the regulations (21 CFR 1040.10(b)15) under the Radiation Control for Health and Safety Act of 1968, as amended, the device also is a Class I medical laser product that incorporates a laser of higher class (Class IIa).

Predicate Devices: Fiberoptic transillumination (FOTI) fiberoptic dental imaging systems – preamendment, various manufacturers

Computer Oral Radiography System (K933455) and CDR-CAM (K963778)
Schick Technologies, Inc.

DIFOTI System for Dental Examinations (K991098),
Electro-Optical Sciences, Inc.

Product Description:
The device known as the DIFOTI USB 2.0 System, also known as the DIFOTI System for Dental Examinations, Model B, is a dental examination system that utilizes visible light from an internal diode laser source, delivered with fiberoptic technology, for transillumination imaging of teeth as a technique for visualizing dental caries. An electronic (CMOS) camera is used to capture the image(s). The light and the camera are connected via a USB 2.0 cable to a small PC that serves for data acquisition and storage, and the computer monitor is used for image visualization.

Indications for Use:
The DIFOTI USB 2.0 System (DIFOTI System for Dental Examinations, Model B) is indicated for detection of frank or incipient caries lesions above the gum line, and for monitoring the progression of such lesions.

Safety and Performance:
Safety and performance testing included image quality evaluation, software/hardware hazard analysis, *in-vitro* vs. *in-vivo* performance evaluation, and software verification and validation.

Conclusion:
Based on the indications for use, technological characteristics, comparison to predicate devices and performance testing, the DIFOTI Dental Examination System has been shown to be safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 9 2004

Michael Greenebaum, Ph.D.
Director of Research
Electro-Optical Sciences, Inc.
1 Bridge Street, Suite 15
Irvington-on-Hudson, New York 10533

Re: K043068
Trade/Device Name: DIFOTI USB 2.0 System
Regulation Number: 21 CFR 872.1745
Regulation Name: Laser fluorescence caries detection device
Regulatory Class: II
Product Code: NTK
Dated: November 4, 2004
Received: November 8, 2004

Dear Dr. Greenebaum:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

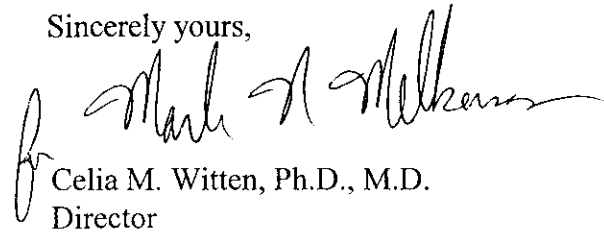
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K043068

Device Name: DIFOTI USB 2.0 System

Indications for Use:

The DIFOTI USB 2.0 System is indicated for detection of frank or incipient caries lesions above the gum line, and for monitoring the progression of such lesions.

Prescription Use X OR Over-the -Counter Use ____
(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K04 3068